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DEPARTMENT OF AGRICULTURE

Food Safety and Inspection Service

[Docket No. FSIS-2016-0021]

Food Safety and Inspection Service Labeling Guideline on Documentation Needed to Substantiate Animal Raising Claims for Label Submission

AGENCY: Food Safety and Inspection Service, USDA.

ACTION: Notice of availability and response to comments.

SUMMARY: The Food Safety and Inspection Service (FSIS) is announcing the availability of an updated version of its guideline on documentation needed to support animal-raising claims made on meat or poultry product labeling. Official establishments submit this documentation to the Agency when they apply for approval of labels with animal raising claims. The updated guideline includes changes made in response to comments on the guideline posted in October 2016. This **Federal Register** notice also summarizes and responds to issues raised in petitions submitted to the Agency by animal welfare advocacy organizations.

DATES: Submit comments on or before **[INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER]**.

ADDRESSES: A downloadable version of the compliance guideline is

available to view and print at

http://www.fsis.usda.gov/Regulations_&_Policies/Compliance_Guides_Index/index.asp. No hard copies of the compliance guideline have been published.

FSIS invites interested persons to submit comments relevant to clarification provided in this notice on the label claim "free range" for poultry products. Only comments addressing this specific issue will be considered at this time. Comments may be submitted by one of the following methods:

- *Federal eRulemaking Portal*: This website provides commenters the ability to type short comments directly into the comment field on the web page or to attach a file for lengthier comments. Go to <http://www.regulations.gov>. Follow the on-line instructions at that site for submitting comments.

- *Mail, including CD-ROMs, etc.*: Send to Docket Clerk, U.S. Department of Agriculture, Food Safety and Inspection Service, 1400 Independence Avenue SW, Mailstop 3758, Room 6065, Washington, DC 20250-3700.

- *Hand- or courier-delivered submittals*: Deliver to 1400 Independence Avenue SW, Room 6065, Washington, DC 20250-3700.

Instructions: All items submitted by mail or electronic mail must include the Agency name and docket number FSIS-2016-

0021. Comments received in response to this docket will be made available for public inspection and posted without change, including any personal information, to <http://www.regulations.gov>.

Docket: For access to background documents or comments received, call (202)720-5627 to schedule a time to visit the FSIS Docket Room at 1400 Independence Avenue SW, Room 6065, Washington, DC 20250-3700.

FOR FURTHER INFORMATION CONTACT: Terri Nintemann, Assistant Administrator, Office of Policy and Program Development by telephone at (202) 205-0495.

SUPPLEMENTARY INFORMATION:

Background

Under the Federal Meat Inspection Act and Poultry Products Inspection Act (21 U.S.C. 601-695, at 601(n), 607; 21 U.S.C 451-470, at 453(h), 457) (the Acts), FSIS develops and implements regulations to require that the labels of meat and poultry products are truthful and not misleading. Under the Acts, the Secretary of Agriculture, who has delegated this authority to FSIS, must approve the labels of meat and poultry products

before the products can enter commerce (21 U.S.C. 601(d); 21 U.S.C. 457(c)).¹

FSIS allows certain labels that bear only mandatory labeling features and that comply with the Agency's labeling regulations to be generically approved (9 CFR 412.2(a)(1)). Generically approved labels do not need to be submitted to FSIS for approval before they can be used on product in commerce. However, a label with a special statement or claim (9 CFR 412.1(c)(3) and 412.1(e)), including an animal-raising claim, must be submitted to FSIS for approval before it may be used on a product distributed in commerce. A label bearing an animal-raising claim must be submitted to the Office of Policy and Program Development, Labeling and Program Delivery Staff (LPDS), in FSIS, with necessary documentation to support the special statement or claim. Examples of animal-raising claims include but are not limited to: "Vegetarian-fed," "Grass-fed," and "Raised without the use of antibiotics."

On October 5, 2016, FSIS announced the availability of and requested comments on its *Labeling Guideline on Documentation Needed to Substantiate Animal Raising Claims for Label*

¹ FSIS has similar authority over egg products under the Egg Products Inspection Act, 21 U.S.C. 1036(b).

Submission (81 FR 68993). FSIS published the guideline to advise establishments of the type of documentation that they should submit in support of animal-raising claims on meat or poultry product labels. FSIS needs this documentation to determine whether these claims are truthful and not misleading.

After reviewing the comments received, the Agency has revised the guideline. A summarized list of major changes to the guideline follows. The revised guideline is posted at: <http://www.fsis.usda.gov/wps/portal/fsis/topics/regulatory-compliance/compliance-guides-index>. The information in this guideline is provided as guidance to assist meat and poultry establishments and is not legally binding from a regulatory perspective. FSIS will update this document, as necessary.

Summarized List of Major Changes to the Guideline

- **Product Labeling: Use of Animal-Raising Claims on the Labels of Meat or Poultry Products**
 - Added information about labeling needed for products bearing claims certified by third-party organization, including when products certified as “organic” need to disclose the certifying entity’s website address on the product label.

- Added information about carrying claims forward on additional products.
- Removed age claims section because establishments are not using these claims.
- Animal Welfare and Environmental Stewardship Claims:
 - Added descriptive language or information (terminology) that should accompany these claims to explain the meaning of the claim to consumers, including the type of information that needs to appear on the label when the product is certified by a third-party organization.
- Breed claims:
 - Added information about carrying these claims forward to other products.
- Living- or Raising-Condition Claims:
 - Reorganized section for clarity regarding labeling terminology and recommended documentation for approval.
 - Added information about additional terminology that typically should accompany these claims to explain the meaning of the claim to consumers, including where the information must appear on the label.
 - Added information on the use of "Free Range" and synonymous claims ("Free Roaming," "Pasture Fed,"

"Pasture Grown," "Pasture Raised," and "Meadow Raised") on labels of poultry products and the documentation needed to substantiate these claims.

- Raised Without Antibiotics - Livestock/Red Meat or Poultry:
 - Added "Raised Antibiotic Free" and "No added antibiotics" as examples of claims that may be used to disclose the fact that animals were not administered antibiotics at any point in the animal production process.
 - Added information on claims that include the term "sub-therapeutic antibiotics" to ensure that consumers understand that the claim means that antibiotics may be administered only in the event of an illness and includes the circumstances for which FSIS will approve labels bearing these claims.
- Raised Without Hormones (No Hormones Administered or No Steroids Administered):
 - Updated information to clarify that a qualifying statement is no longer required on pork products labeled as having been raised without hormones because Federal law permits the use of certain hormones in swine, e.g., for gestation.
 - Added new examples of this type of claim.

- Added information to clarify why a qualifying statement is necessary for products made from a kind or species for which Federal law prohibits hormone use and to emphasize that this statement must be prominently- and conspicuously- displayed on the label, as verified by FSIS.
- Third-Party Certification:
 - Added information about documentation needed to support labels bearing animal raising claims that have been “Verified” or “Certified” by third party organizations.
 - Added information about “organic” claims, including other claims that could be substantiated with an organic certificate.
- Added a section on procedures for adding an additional supplier for a label with animal-raising claims that was previously approved by FSIS.

Comments and FSIS Responses

FSIS received over 4,600 comments on the *Labeling Guideline on Documentation Needed to Substantiate Animal Raising Claims for Label Submission*. The majority are similar comments or groups of comments from individuals who made them as part of what appears to be organized write-in campaigns. FSIS received thirty individual comment letters from animal-welfare advocacy

organizations, consumer advocacy organizations, trade associations representing the poultry, poultry and meat, egg, or organic industry, beef marketing companies, organizations that provide third-party certification services, agriculture-specific coalitions/cooperatives, producers, and an environmental advocacy organization.

Comments from two animal welfare advocacy organizations also included over 87,000 and 35,000 signatures, respectively. FSIS also received a spreadsheet with similar comments opposing the guidance from 15,477 members of an animal welfare advocacy organization.

Comments from trade associations representing the poultry and meat industry generally found the information in the guideline to be helpful to establishments. Other comments, including those participating in the various write-in campaigns, strongly opposed parts of the guideline, as well as FSIS's general label approval procedures for animal-raising claims.

FSIS also received petitions from animal welfare organizations that raise issues associated with animal-raising claims similar to the issues raised by many of the comments. Therefore, the comment summaries and FSIS's responses address the issues raised in the petitions.

Following is a summary of the issues raised in the comments and petitions and FSIS's responses.

Regulatory Guidance and Administrative Procedure Act

Comment: Animal-welfare and consumer advocacy organizations asserted the Agency is violating the Administrative Procedure Act (APA) by effectively promulgating "requirements" for establishments without following due notice-and-comment procedure. They said that FSIS should follow the APA procedures because the guideline "grants rights, imposes obligations, and produces significant effects on private interests."

Response: The guideline does not promulgate new requirements subject to notice-and-comment requirements under the APA. As noted above, under 9 CFR 412.1(c) and (e), labels bearing animal-raising claims are required to be submitted to FSIS for prior approval. FSIS published the guideline to assist establishments that manufacture meat and poultry products labeled with animal-raising claims to prepare their label approval applications and to facilitate FSIS's review of labels bearing animal-raising claims. Animal raising claims are voluntary marketing claims, and establishments are not required to use any of the claims listed in the guideline. However, if

they do, establishments may refer to the guideline to help them provide the documentation that FSIS needs to evaluate labels bearing animal raising claims and to determine whether such claims are truthful and not misleading.

Notably, FSIS has sought to engage the public in the consideration and revision of the guideline and has provided extensive opportunity for public comment. We have made many substantive changes based on the comments we have received. We also note that this is not a novel approach. FSIS routinely publishes guidance on how FSIS interprets labels to be truthful or not misleading, with examples of acceptable supporting documentation.

Defining Animal-Raising Claims

Comment: Animal-welfare advocacy organizations, consumer-advocacy organizations, petitioners, and individuals, said that FSIS must define animal-raising claims in the regulations and not allow the use of animal-raising claims that are not defined in the regulations.

Response: FSIS disagrees that it needs to establish codified definitions for animal raising claims to prevent product misbranding. Animal production practices vary and are continuously developing; maintaining a current list of codified

allowable claims would be impractical. Further, FSIS does not have the authority to regulate on-farm animal production and thus its codification of animal raising claims could inappropriately restrict developments in animal production practices by operations that would benefit from the use of a truthful claim.

The Acts and implementing regulations prohibit the sale and distribution of "misbranded" meat and poultry products, i.e., meat and poultry products bearing labels that are misleading or untrue (21 U.S.C. 453(h)(1); 21 U.S.C. 601(n)(1), implemented at 9 CFR Parts 381.129 and 317.8, respectively). Accordingly, FSIS is responsible for ensuring that the labeling of meat, poultry, and egg products is truthful and not misleading. To prevent labeling claims that are false and misleading, any label with a special statement or claim, including an animal-raising claim, not defined in FSIS regulations or the *Food Standards and Labeling Policy Book* must be submitted to FSIS for prior-approval (9 CFR 412.1(c)(3) and 412.1(e)). As part of the label approval process, FSIS verifies the accuracy of the special statement or claim by reviewing supporting documentation submitted with the label approval application.

Consistent with this approach, FSIS evaluates labels bearing animal-raising claims on a case-by-case basis by reviewing the animal production protocol submitted with the label approval application. FSIS approves the label if the documentation supports the claim made, if the claim is truthful and not misleading, and if the claim (including any qualifying information) is prominently- and conspicuously-displayed on the label. At establishments that label product with animal raising claims, FSIS inspectors verify that establishments have FSIS label approval on file. In addition, they are to take the appropriate regulatory control action, such as retention of product, when they determine that misbranded product would otherwise enter commerce (i.e., it is shipped from the establishment). FSIS could also rescind approval of false or misleading labels per 9 CFR 500.8. Under this approach, FSIS is able to prevent the sale of misbranded meat and poultry products by ensuring that labels bearing animal-raising claims accurately reflect the conditions under which the source animal was raised.

Consistency with other Federal Agency Standards

Comment: An animal-welfare advocacy organization argued that FSIS's labeling standards must be in harmony with Federal Trade Commission (FTC) and Securities and Exchange (SEC)

standards, and that the Agency should consult with the FTC and SEC in the rulemaking that it ought to be carrying out following APA procedures. Several advocacy organizations asserted that inconsistently defined claims are inherently "false and misleading in any particular," and therefore misbranded under the Acts.

Response: The labeling requirements for meat and poultry products in the Acts and implementing regulations are aimed at preventing product misbranding. For the reasons given previously, FSIS considers its review and approval of labels bearing animal-raising claims, under the conditions described in the guideline, to provide sufficient assurance that product labeling bearing claims is not be false or misleading in any particular. As a result, the products will not be misbranded.

FSIS is aware of the statutory authorities under which the FTC and SEC operate to require substantiation of claims companies make about their products. For example, Section 12 of the Federal Trade Commission Act (15 U.S.C. 52) prohibits false advertisement of foods, drugs, and cosmetics. FSIS generally coordinates its activities with the FTC and other agencies to avoid duplication of effort and advises companies to consult FSIS labeling regulations, rules, and policies when developing

advertising for meat and poultry products. (On coordination with the FTC, See *A Guide to Federal Food Labeling Requirements for Meat, Poultry, and Egg Products* (FSIS/USDA, Washington, DC, 2007)).

Third-party Certification

Comment: Comments from animal welfare advocacy organizations, consumer advocacy organizations, individuals, organizations that provide third-party certification, and producers argued that, because FSIS does not conduct on-farm verifications, the Agency should require animal-raising claims to be verified by a third-party certifying organization. These commenters stated that the required certification would constitute evidence that the claim is truthful and meets consumer expectations for the claim. Several commenters included their recommendations for third-party certification programs that they believe reflect consumer expectations for these claims.

Response: FSIS believes it would not be economically feasible for many small and very small establishments to incur the additional costs of independent third-party certification because of their low sales volumes. FSIS also believes that requiring third-party certification could reduce the variety of

products labeled with animal-raising claims these establishments would have to offer. Reductions in purchase options could also result in a cost to consumers. FSIS believes that its current procedure, which provides for case-by-case review of the producer's animal-raising protocol, is effective in ensuring that labels bearing animal-raising claims are truthful and not misleading. While the Agency has determined that it will not require independent third-party certification for all animal-raising claims, this determination should not in any way diminish the utility of third-party certifying organizations. Establishments can choose to use third-party certification programs to support animal raising claims on labels.

Font Size for Claim Statements

Comment: Animal-welfare and consumer-advocacy organizations urged FSIS to set minimum type sizes for animal-raising claims and any additional text or qualifying information on the label that explains the claims. They said this information is often so small that it goes unnoticed.

Response: When the disclosure of qualifying information is necessary to prevent a claim from being false and misleading, FSIS agrees the information must be presented truthfully on the label. FSIS also agrees such information must be prominently-

and conspicuously-displayed on the label and in terms likely to be read and understood by the ordinary individual (21 U.S.C. 601(n)(6); 21 U.S.C. 453(h)(6), implemented at 9 CFR 317.2(b) and 381.116(b), respectively). To that end, through its label prior-approval program, FSIS confirms that any qualifying information consists of clear language, that its type is prominent and conspicuous (as compared to with other words, statements, or designs on the label), and that it is placed on the same panel of the package as the claim being qualified.

As discussed below, several comments expressed concern that claims associated with hormone use during animal production may be particularly misleading to consumers, particularly when hormones are not allowed during the production of certain species. To address these concerns, FSIS has updated the guideline to clarify why qualifying information is necessary on certain products and to emphasize that this information must be prominently- and conspicuously-displayed on the label for FSIS to approve the claim. This specific issue is discussed in more detail below.

Posting of Company-specific Information

Comment: Commenters urged FSIS to make establishments' supporting documentation public, preferably in an open, online

format.

Response: Developing and maintaining a public database of supporting documentation for establishments' claims would be overly cumbersome for FSIS. However, interested persons can submit a request for copies of any records not normally prepared for public distribution in accordance with the Freedom of Information Act (FOIA) (5 U.S.C. 552). Please note that certain records may be withheld in whole or in part from the requestor if they fall within one of nine FOIA exemptions. For example, Exemption 4 protects trade secrets and confidential commercial or financial information.

Organic Certification

Comment: Producers, a coalition that promotes sustainable agriculture, a trade association representing organic producers, and a foreign beef marketing agency urged FSIS to consider organic certificates to be sufficient support for other animal-raising claims, such as "no antibiotics administered." The comments said additional documentation, e.g., a segregation protocol, is unnecessary for certain claims and is an undue burden on certified-organic producers. Similarly, a trade association representing the poultry industry asked FSIS to state whether third-party program certificates, other than

organic certificates, may be used in place of the documentation listed in the guideline.

Response: Any agricultural product that is sold, labeled, or represented as "organic" must be produced in accordance with the Agricultural Marketing Service's (AMS) National Organic Program (NOP) regulations in 7 CFR 205, as verified by a NOP-accredited third-party certifier. Therefore, if an establishment produces meat or poultry products that qualify for an organic claim under the NOP regulations, the establishment may not need to provide FSIS with additional documentation to support a separate animal-raising claim if the standards for the animal-raising claim are supported by the organic claim, i.e., the standard for the animal-raising claim is explicitly addressed in the NOP regulations. For example, the organic certificate would be sufficient support for the claim "no antibiotics administered" on certified organic livestock products, because 7 CFR 205.238(c)(1) explicitly prohibits antibiotics for this purpose. Furthermore, a written description of the product tracing and segregation mechanism would not be needed as support for certified organic products because these activities are a condition of NOP certification.

For meat and poultry products certified under non-NOP

third-party organization programs involving separate animal-raising claims, such as Global Animal Partnership's 5-Step Certification Program, FSIS would likewise accept their certificate as support for separate animal-raising claims or in place of the documentation listed in the guideline.

FSIS has updated the guideline by indicating the circumstances for which an organic certificate could also be used to support a specific animal-raising claim or in place of the documentation listed in the guideline. We would again note, however, that establishments are not required to use any animal-raising claim, including those listed in the guideline.

Support for Claims; Company Information

Comment: Animal welfare advocacy organizations and individuals opposed FSIS's approving animal-raising claims based on what the commenters consider to be "minimal support," e.g., a brief affidavit from the entity making the claim. Instead, they urged FSIS to stipulate, at a minimum, detailed animal-care protocols and photographic evidence when making any label approval determination.

Response: For FSIS to approve an animal-raising claim, an establishment must submit to FSIS documentation that supports the claim. The kind and amount of supporting documentation

depends on the claim and could vary according to circumstances. FSIS comprehensively evaluates these label applications on a case-by-case basis. Further, FSIS often consults with its Federal partners, e.g., the USDA's AMS, to decide whether the documentation submitted in support of an animal-raising claim provides the level of detail needed to ensure that the claim is truthful and not misleading. The type and amount of supporting documentation needed to adequately support an animal-raising claim varies with the type of claim being made. There are a few claims, such as "made from Angus beef," that could be supported with a brief affidavit, e.g., a certificate from a breed organization, when the establishment produces only those products. However, that is not necessarily the case for all animal-raising claims.

Animal Welfare and Environmental Stewardship

Comment: FSIS received several comments from animal welfare advocacy organizations, consumer advocacy organizations, and individuals on the Agency's guidance on animal welfare and environmental stewardship claims. Additionally, in May 2014, before FSIS published the 2016 guidance, the Animal Welfare Institute (AWI) petitioned the Agency to amend its regulations to require third-party certification for the approval of animal

welfare and environmental stewardship claims in the labeling of meat and poultry products.² Both the comments and petition asserted that FSIS does not have the expertise or resources to adequately approve animal welfare and environmental stewardship claims. According to the comments and petition, the Agency currently approves claims based on standards that do not meet consumer expectations. To address these concerns, the comments and the petition stated that FSIS should only approve animal welfare and environmental stewardship claims that have been certified by an independent third-party certifying organization that has established standards that exceed the conventional industry standards defined by meat and poultry trade associations.

Response: FSIS disagrees. As noted in the guideline, animal welfare and environmental stewardship claims describe how animals are raised based on the care they receive by the producer or how the producer maintains the land and replenishes the environment. The issues raised in the comments and petition show that consumers, producers, and certifying entities have

²FSIS denied the petition on February 22, 2019. The petition and FSIS's response are available on the FSIS petitions webpage at: <https://www.fsis.usda.gov/wps/portal/fsis/topics/regulations/petitions>.

different views on the specific animal production practices that should be associated with certain animal welfare or environmental stewardship claims. Thus, because animal welfare or environmental stewardship claims mean different things to different people, a claim that is defined by a specific third-party certifying organization's animal-raising standards cannot reflect the diverse views associated with these types of claims.

To ensure that animal welfare and environmental stewardship claims continue to accurately reflect the animal production practices that define a specific claim, FSIS has updated its guidance with additional information on, as well as examples of, animal welfare and environmental stewardship claims for which the Agency is likely to find their use to be truthful and not misleading. Specifically, the guideline provides for the approval of animal welfare and environmental stewardship claims if the product label also describes the animal-raising standards that define the claim and identifies the entity that established the standards, e.g., "Raised with Care: TMB Ranch Defines Raised with Care as [explain the meaning of the claim on the label]." If the entity has a website that describes the standards used to define the claim, the label may provide the website address instead of explaining what the claim means on the product label,

e.g. "Raised with Care as defined by TMB Ranch at [website address].

As an alternative to the additional terminology, animal welfare and environmental stewardship claims can be certified by a third-party certifying organization that posts the standards used to define the claim on its website. If the claim is certified by a third-party certifying organization, FSIS will approve the label bearing the claim if it includes the certifying entity's name, website address,³ and logo, when the organization has a logo, as described in the guideline. Under this approach, the labeling of a meat or poultry product that bears an animal welfare or environmental stewardship claim includes the information that consumers need to determine whether the animal-raising practices used to define a particular animal claim meets their expectations for the claim.

Comment: Comments from animal welfare advocacy organizations and consumer advocacy organizations stated that although FSIS will only approve animal welfare or environmental stewardship claims if the claim is defined on the labeling, companies have different standards for defining animal welfare

³ Products certified as "organic" would not need to disclose a website address on the label, except when the address is required under 7 CFR Part 205.

and environmental stewardship, and they use different types of documentation to support these claims. The comments stated that because of these differences, the same claim may reflect different practices depending on the producer's standards for the claim, which, according to the comments, results in claims that are misleading and confusing to consumers. The comments also asserted that it is unlikely that a producer's "humane" or "sustainable" practices can be adequately described in the limited space provided on a product label.

Response: As discussed above, FSIS recognizes that the same animal welfare or environmental stewardship claim may reflect different animal production practices depending on the producer's or certifying entity's standards for the claim. However, FSIS disagrees that these differences result in claims that are misleading or confusing to consumers. As noted above, FSIS has updated the guideline with additional information on and examples of claims the Agency will likely find to be truthful and not misleading if accompanied by the appropriate documentation. The labels of products bearing animal welfare and environmental stewardship claims need to include information that consumers can use to determine whether the animal-raising practices used to define a particular claim meet their

expectations for the claim, i.e., the name of the entity that established the standard with a statement explaining the meaning of the claim as applied to that particular product or a website address that provides the entity's standards for defining the claim. If a third-party certifying organization established the claim, the website address would need to provide the certifying organization's standards for defining the claim. FSIS will not approve an animal welfare or environmental stewardship claim if the product label does not include complete information on the animal-raising standards that define the claim or identify the entity that established the standards. Or, if the claim was certified by a third-party certifying organization, FSIS will not approve the label bearing the claim if it does not include the certifying entities name, website address, and logo, when the organization has a logo.

Comment: The above comments and the 2014 AWI petition stated that many animal welfare and environmental stewardship claims are misleading because they reflect conventional industry standards defined by meat and poultry trade associations. The comments and petition both referenced surveys that, according to the comments and petition, show that consumers believe animal welfare claims, such as "humanely raised," represent a standard

of care higher than that of the conventional animal agriculture industry. Specifically, they stated that surveys show that a majority of consumers believe that products that bear "humanely raised" claims in their labeling should be derived from animals that have access to the outdoors and adequate space to move about freely. They asserted that FSIS should only approve third-party certified claims if the party employs standards that align with these consumer expectations for the claim in question. The comments and petition included examples of certification programs that they believe meet consumer expectations for animal welfare claims.

Response: As noted above, FSIS will only approve labels of products bearing animal welfare and environmental stewardship claims that include information that consumers need to determine whether the animal-raising practices used to define a particular claim meet their expectations for the claim. Thus, consumers who have specific expectations for the standard of care used to define a claim may identify meat and poultry products that meet their expectations from the information included in the product's labeling.

Comments: The 2014 AWI petition and comments from animal welfare advocacy organizations stated that the current guideline

places producers who choose to use third-party certification at an economic disadvantage. The comments noted that producers who choose to use a third-party certification typically incur costs associated with the certification and in maintaining systems that go beyond conventional production standards in terms of animal welfare and environmental stewardship. The comments and petition said that producers who make animal welfare or environmental claims that are not independently certified can make the same claims and charge a premium for their products while avoiding the cost of certification and production. They also asserted that requiring third-party certification will increase consumer confidence in animal welfare and environmental stewardship claims because third-party certification programs are independent of the companies they are certifying and have expertise in establishing standards.

Response: FSIS disagrees that the guideline places companies that choose to use third-party certification for animal raising claims at an economic disadvantage. A producer's decision to use a third-party certifying organization's certification program is a voluntary business decision. Producers that use certifying entities do so because they have determined that the benefits of labeling a meat or poultry

product with a certified animal welfare or environmental stewardship claim outweigh the cost associated with the certification program. Consumers who have more confidence in claims that have been certified by a third-party organization can identify products that meet a certifying entity's standards from the information included in the product's labeling.

However, as noted above, FSIS disagrees that third-party certification be required because the Agency believes it would not be economically feasible for many small and very small establishments to incur the additional costs of independent third-party certification because of their low sales volumes. In addition, because FSIS reviews all animal raising claims on a case-by-case basis, the Agency does not believe that it is necessary to require third party certification to ensure that labels bearing animal welfare and environmental stewardship claims are truthful and not misleading.

Diet

Comment: A producer urged FSIS to only accept the term "grassfed" and not the terms "Grass Fed" or "grass-fed."

Response: FSIS considers all three terms synonymous and will continue to approve them when adequate documentation is provided to substantiate the claim.

Comment: A producer urged FSIS to require that official establishments submit to FSIS annual monitoring and reporting of soil health as a condition for approval of "grass-fed" claims. The commenter argued that requiring the data will promote better land management practices and healthy grasslands.

Response: FSIS believes that information about land management practices is not necessary for the Agency to evaluate "grass-fed" claims in the labeling of meat and poultry products because land management practices are not part of the animal's diet. However, land management practices information may be included as a part of the supporting documentation if the claim includes information about soil health or other land management practices.

Comment: An environmental advocacy organization urged FSIS to establish a standard for "grass-fed" based on four conditions: (1) no confinement; (2) no routine antibiotics; (3) no added hormones; and (4) a forage-based diet throughout the lifetime of the animal after weaning. Likewise, comments from consumers, animal advocacy organizations, and consumer advocacy groups requested that FSIS establish a standard for "grass-fed" that is applicable from weaning to slaughter, prohibits the use of

feedlots, and for which animals have 100 percent access to a forage-based diet. In addition, an animal welfare advocacy organization asked that FSIS clarify whether products made from animals with less than 100 percent access to grass or forage can bear "grass-fed" label claims, such as 85 percent grass-fed.

Response: In response to these comments, FSIS has updated the guideline to clarify that "100% grass-fed" claims are not permitted for animals raised on feedlots. FSIS has also added that when animals have less than 100 percent access to grass or forage, any "grass-fed" claim must accurately reflect the circumstances of raising (e.g., "Made from cows that are fed 85% grass and 15% corn"). Similar to other dietary claims, FSIS will verify these claims by reviewing records that describe the animal's diet from birth to harvest or the period of raising being referenced by the claims. With these changes, FSIS believes the information in the guideline is adequate as it relates to use of "grass-fed" and "100% grass-fed" label claims. As outlined in the guideline, for FSIS to approve these particular claims, animals must be fed only grass or forage, with the exception of milk consumed before weaning. In addition, these animals cannot be fed grain or grain byproducts and must have continuous access to pasture during the growing season

until slaughter.

Living/Raising/Raising Conditions

Comment: Comments from animal welfare advocacy organizations, consumer advocacy organizations, and individuals stated that FSIS should update the guideline on claims related to living/raising conditions by defining separate "range" and "pasture" claims for meat and poultry products, by defining "crate free," and other similar claims. The comments noted that under the guideline, certain claims, such as "Free Range" and "Pasture Raised" require the producer to define the claim on the product label, while other claims, such as "Free Roaming" and "Pasture Grown," are acceptable without a definition when the animal from which the products are derived has continuous access to the outdoors for a minimum of 120 days per year. The comments stated that FSIS should set minimum standards that reflect consumer expectations for these claims and clarify whether certain claims may only be used for products derived from livestock or birds. The comments included recommendations on how to define "range" or "pasture" claims for birds and separate recommendations on how to define "range" or "pasture" claims for livestock. According to the comments, the recommended standards included in the comments reflect consumer expectations for these

claims, which include some degree of vegetative cover, a minimum amount of space per animal, and protection from risks to animal welfare.

Response: As explained above, FSIS does not believe that the Agency should define specific living/raising conditions claims in the regulations or in guideline because our current procedure, which provides for case-by-case review of the producer's animal-raising protocol, is effective in ensuring that labels bearing these claims are truthful and not misleading. However, these comments showed confusion regarding the labeling of products with living/raising conditions claims. To ensure that living/raising conditions claims continue to accurately reflect the animal production practices that define a specific claim, FSIS updated the guideline by reorganizing the living/raising conditions section to make clear which claims do not require additional terminology and the documentation that is needed to substantiate these claims.

In addition, FSIS added information to clarify that nearly all living/raising conditions claims require additional terminology explaining the meaning of the claim, e.g., "Cage free. Chickens were never confined to cages during raising." FSIS also clarified that, as an alternative to the additional

terminology, living/raising claims can be certified by a third-party certifying organization that posts its standards for defining the claim on its website. If the claim is certified by a third-party certifying organization, FSIS will only approve the label bearing the claim if it includes the certifying entity's name, website address, and logo, when the organization has a logo, as described in the guideline.

Based on consultations with AMS in the 1990s, FSIS determined that additional terminology is not needed on the label for the claim "Free Range" and synonymous claims ("Free Roaming," "Pasture Fed," "Pasture Grown," "Pasture Raised," and "Meadow Raised") on poultry products. However, for FSIS to approve these claims, additional information must be submitted to substantiate the claim. Specific details about what additional information is needed have been added to the guideline. Although FSIS believes its current approach is adequate because it can accommodate various production situations while still providing for an animal-raising environment that allows birds to express natural behaviors, FSIS requests comments on this approach.

Comment: In January 2016, AWI submitted a different

petition⁴ requesting that FSIS initiate rulemaking to define "free range" and equivalent claims for poultry and to establish substantiation requirements for the approval of these claims. As an alternative, the petition requested that FSIS update its guidance on "free range" claims to incorporate the changes requested in the petition.

The petition asserted that outdoor access should not be the sole defining factor of the "free range" claim. According to the petition, in order for a producer to properly illustrate that their birds are free range, they should be required to address several living conditions in addition to outdoor access. The petition stated that producers should be required to provide evidence that birds have easy, continuous access to vegetation, shade, and soil; protection against predators and adverse weather; and an outdoor space that is at least as large as the indoor space. According to the petition, only when producers are required to provide this information does this claim become valuable for consumers.

The petition and other commenters stated that the current guideline does not reflect consumer expectation because, under

⁴ The petition is available at <https://www.fsis.usda.gov/wps/wcm/connect/368eba0b-4195-4641-91d7-7f772ead9a3e/16-01-AWI-Petition-012016.pdf?MOD=AJPERES>.

the guideline, poultry labeled as "free range" may come from birds raised indoors under crowded conditions, as long as the birds have access to the outside. The comments and petition stated that the current guideline and approval process for "free range" poultry claims results in claims that are inconsistent and misleading to consumers.

Response: As noted above, FSIS has updated the guideline by adding information on the type of documentation typically needed to substantiate a "free range" claim on poultry products. The update reflects FSIS's longstanding policy for approving these claims. For FSIS to approve this specific claim, the establishment must include a description of the housing conditions of the birds, as well as demonstrate the birds have continuous, free access to the outside.

Comment: Comments from animal welfare advocacy organizations stated that "cage free" claims should not be allowed on chicken and turkey products because birds raised for food are not typically kept in cages before being transported to slaughter. The comments asserted that "cage free" claims on poultry products are misleading because they give consumers the false impression that there are poultry products in the market that came from caged birds.

Response: When supported by documentation, the claim that birds were "raised cage free" is a true and accurate statement about a producer's raising practices that the establishment has chosen to communicate to consumers on the product label. If the claim is factually accurate and supported by documentation, FSIS will approve a "cage free" claim in the labeling of poultry products if it is part of a complete claim that is truthful and not misleading, e.g., "Cage free. Chickens were never confined to cages during raising." Any producer that raises poultry without cages may label their poultry products as "cage free" if the claim is substantiated by documentation. Even if raising birds as cage free is a common practice, that fact does not make the claim false or misleading.

Raised without Antibiotics

Comment: A group of animal welfare advocacy organizations noted that the guideline allows producers to make a number of voluntary claims with respect to antibiotic use during animal production but does not require that producers disclose antibiotic use. The comments asserted that FSIS must require that antibiotic use during animal production be disclosed in the labeling of meat and poultry products to prevent product misbranding and foster informed consumer decision making.

In addition, in June 2013, before FSIS published the initial guideline, the Animal Legal Defense Fund (ALDF) petitioned FSIS to initiate rulemaking to require mandatory labeling to disclose routine antibiotic use in animals used to produce meat and poultry products.⁵ The petition requested that FSIS require that the labels of all meat and poultry products disclose whether the source animals were administered antibiotics. The petition included a study that suggests that bacteria found in meat from animals raised with antibiotics may be more likely to be resistant to antibiotics than bacteria in meat from animals raised without antibiotics. The petition also referenced surveys that showed that consumers are concerned about issues related to the use of antibiotics in animal production and the development of antibiotic resistant strains of bacteria.

The petition and the comments asserted that the current regulatory scheme, which allows producers that do not use antibiotics to voluntarily disclose this fact on the product labeling, fails to provide uniform, meaningful disclosure of antibiotic use on the farm. Both the petition and comments

⁵ The petition is available at https://www.fsis.usda.gov/wps/wcm/connect/12aeca93-4d3e-4ac7-b624-d5fc0b0dbae0/Petition_Animal_Legal_Defense_Fund_060313.pdf?MOD=AJPERES.

stated that the failure to disclose material facts about antibiotic use prevents consumers from making informed purchasing choices with respect to an animal production practice that many consumers believe presents a threat to public health.

Response: FSIS does not require that the labeling of meat and poultry products disclose the fact that antibiotics were administered to animals as part of the production process because the Agency does not consider animal production practices to be material facts that must be disclosed in the product label. Animal-raising claims, including claims about antibiotic use, are voluntary marketing claims that highlight certain aspects about the way source animals used to produce meat and poultry product were raised. These claims do not provide information on the characteristics or components of the meat or poultry products themselves.

FSIS conducts testing for residues in meat and poultry to verify that product does not include any prohibited chemical, including antibiotics. As discussed above, FSIS regulates the marking, labeling, and packaging of meat and poultry products to ensure that these products are not misbranded. Under the Acts, a product is misbranded, among other circumstances, if its labeling is "false and misleading in any particular" (21 U.S.C.

601(n)(1), 21 U.S.C. 453(h)(1)). FSIS has historically interpreted "false or misleading in any particular" to be a material misrepresentation directly related to the inherent characteristics of the food itself.⁶ In other words, the elements required to appear on the label must inform the consumer of the constituents of the product. Information that may be of interest to certain consumers, such as the use of antibiotics in animal production, but that does not pertain to the product's nutritional, organoleptic, or functional characteristics, or any other essential attributes of the food, is not considered a "material fact" that must be disclosed in the product's labeling. Although the 2013 petition submitted by ALDF includes information to demonstrate that the administration of antibiotics as part of the animal production may lead to the development of antibiotic resistant strains of bacteria, the supporting data do not demonstrate that the proper use of antibiotics in animal production affects the attributes of the meat or poultry product itself.

As noted in the petition, most major grocery stores carry meat and poultry products labeled as "antibiotic-free." Thus,

⁶ See FSIS's final response to petition #12-02 submitted by SOIA available at: <https://www.fsis.usda.gov/wps/wcm/connect/dcda4cb4-2612-4283-a9a7-0f97d976e022/12-02-FSIS-Final-Response-090916.pdf?MOD=AJPERES>.

consumers who want to avoid purchasing meat and poultry products from animals that may have received antibiotics during the production process can identify these products from current voluntary animal production claims. FSIS is currently testing certain products with "raised without antibiotics" claims to verify that those products are not misbranded. This effort will help ensure that such label claims are accurate and not misleading.

Comment: The 2013 ALDF petition and consumer advocacy organizations stated that FSIS must adopt a uniform labeling standard for all meat and poultry products to disclose whether animals were fed antibiotics. The comments stated that the guideline provides for producers to make a number of voluntary claims, such as "No Antibiotics Administered," "No Antibiotics Ever," "Raised without Sub-therapeutic Antibiotics," and "No Antibiotics Administered the last 150 days," which the comments believe make it difficult for consumers to make informed decisions on what they consider to be public health issues. The petition recommended that FSIS prescribe standard terminology and definitions for the claims "Raised with Antibiotics," "Raised without Antibiotics," and "Given Antibiotics for Therapeutic Antibiotic Use Only." Finally, according to the

commenters and the petition, antibiotic claims need to be set apart from other animal-raising claims on the label because the use of antibiotics in animal agriculture has potential human health consequences that make labeling clarity particularly important.

Response: FSIS believes that its current case-by-case approach for the approval of labels bearing claims on the use of antibiotics during animal production is effective in ensuring that these types of claims are truthful and not misleading. Therefore, the Agency is not establishing standard definitions for these types of claims as recommended by the comments and petition.

FSIS will approve a label bearing an animal-raising claim related to antibiotic use if the claim is supported by documentation and the claim accurately reflects the conditions under which the source animal was raised. As noted by the comments, FSIS approves claims that reflect variations in the use of antibiotics during animal production, such as "raised without antibiotics" and "no antibiotics administered for growth promotion, antibiotics administered in the event of illness." The variations in claims reflect differences in the use of antibiotics during animal production. FSIS disagrees that these

claims are misleading or confusing to consumers because FSIS will only approve a claim associated with antibiotic use that accurately reflects the conditions under which the source animal was raised.

Comment: Several comments from consumer advocacy organizations and individuals said FSIS should prohibit the claim "raised without sub-therapeutic antibiotics" because the term "sub-therapeutic" has no commonly recognized meaning.

Response: FSIS will only approve claims that animals have not been administered sub-therapeutic antibiotics if such claims are part of a complete claim that is truthful and not misleading, e.g., "No sub-therapeutic antibiotics. Animals do not receive antibiotics on a daily basis; animals only receive antibiotics in the case of illness." However, to avoid related confusion, FSIS updated the guideline to include additional examples of claims where the Agency is likely to find the use of the term "sub-therapeutic" to be truthful and not misleading.

Raised without Added Hormones

Comment: Several comments from consumers, animal advocacy organizations, consumer advocacy organizations, and an environmental advocacy organization urged FSIS to establish standards in the guideline for the claim "raised without growth

promotants (stimulants)." According to the comments, FSIS should approve the claim only if the source animals were not treated with or fed any chemical compound used for growth promotion and feed efficiency, including, but not limited to, hormones, beta-agonists, and antibiotics.

Response: FSIS agrees that documentation for the claim "raised without growth promotants (stimulants)" would need to demonstrate that the animals were not treated with or fed any chemical compound used by producers for growth promotion and feed efficiency throughout the life of the animal. However, in FSIS's experience, use of this specific claim is rare. Therefore, FSIS has not made any changes related to its expectations for growth promotant claims but has updated the examples in the guideline with more commonly used negative hormone claims, like "Raised without Added Hormones" and "No added Hormones Administered."

Comment: A consumer advocacy organization said FSIS should no longer stipulate the qualifying statement "Federal regulations prohibit the use of hormones in (species)" on pork products labeled with a negative hormone claim. "The organization argued the statement is misleading on these products because several hormones, e.g., Altrenogest, a synthetic progestin, and

Oxytocin, have been approved for use in swine by the Food and Drug Administration.

Response: FSIS agrees with the comment and has updated the guideline to clarify that the qualifying statement is no longer applicable to pork products. To be clear, a qualifying statement will still be required on products made from poultry, veal, calf, goat, mature sheep, or exotic (non-amenable) species bearing a negative hormone claim, such as "raised without added hormones."

Establishments do not need to resubmit their labels for approval to remove the qualifying statement from pork product labels. Establishments can remove the qualifying statement generically under 9 CFR 412.1, e.g., at next printing, to be consistent with FSIS's updated guideline.

Comment: Several comments from animal advocacy organizations and an environmental advocacy organization urged FSIS to prohibit negative hormone claims on products made from species for which Federal law prohibits hormone use. They argued that allowing such claims may mislead consumers who may be unaware that hormones are not to be used even in animals whose products do not bear the claim.

Response: If the claim is factually accurate and supported by documentation, the guideline explains FSIS will approve a negative hormone claim on products made from poultry, veal, goats, mature sheep, and exotic species (such as buffalo and elk) when accompanied with the following qualifying statement on the label: "Federal regulations do not permit the use of hormones in [name the species or kind]." As explained above, this information must be prominently- and conspicuously- displayed on the label in accordance with the regulations.

However, FSIS acknowledges consumers who are unaware that hormones are prohibited for use in certain livestock and poultry species could potentially be misled by a negative hormone claim due to its unique nature. To address this concern, FSIS has updated the guideline to clarify why the qualifying information is necessary on certain products. The guideline was also updated to emphasize that FSIS only approves these claims when the necessary qualifying information is prominently and clearly displayed on the label, e.g., it appears directly adjacent to the claim or is in type at least one-third the height.

Congressional Review Act

Pursuant to the Congressional Review Act at 5 U.S.C. 801 et seq., the Office of Information and Regulatory Affairs has

determined that this notice is not a "major rule," as defined by 5 U.S.C. 804(2).

Additional Public Notification

Public awareness of all segments of rulemaking and policy development is important. Consequently, FSIS will announce this **Federal Register** publication online through the FSIS Web page located at: http://www.fsis.usda.gov/federal-register_. FSIS will also announce and provide a link to it through the FSIS *Constituent Update*, which is used to provide information regarding FSIS policies, procedures, regulations, **Federal Register** notices, FSIS public meetings, and other types of information that could affect or would be of interest to our constituents and stakeholders. The Constituent Update is available on the FSIS Web page. Through the Web page, FSIS is able to provide information to a much broader, more diverse audience. In addition, FSIS offers an email subscription service which provides automatic and customized access to selected food safety news and information. This service is available at: <http://www.fsis.usda.gov/subscribe>. Options range from recalls to export information, regulations, directives, and notices. Customers can add or delete subscriptions themselves, and have the option to password protect their accounts.

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Done at Washington, DC:

Carmen M. Rottenberg,
Administrator.

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